NOV 2 5 2008

K082949 Page 1/1

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:

OrthoPediatrics, Corp.
210 N. Buffalo Street
Warsaw, Indiana 46580
Establishment Registration No.: 9102640

510(K) CONTACT:

Gary Barnett
VP-Regulatory & Medical Affairs
Tel: (574) 268-6379
Fax: (574) 269-3692

TRADE NAME: OrthoPediatrics Bone Screws

COMMON NAME: Cortical, Cancellous and Cannulated Bone Screws

CLASSIFICATION: 21 CFR 888.3040 Bone Fixation Screw: Class II per 21 CFR §888.3040

DEVICE PRODUCT CODE(S): HWC

SUBSTANTIALLY EQUIVALENT DEVICES:

Synthes (K002271), Synthes (USA)
Synthes (K012945), Synthes (USA)
Synthes (K021932), Synthes (USA)
Synthes (K043185), Synthes (USA)
Synthes (K962011), Synthes (USA)
Synthes (K962823), Synthes (USA)
Synthes (K963172), Synthes (USA)
Synthes (K963192), Synthes (USA)
Biomet (K984209), Biomet, Inc.
I.T.S. (K043410), I.T.S.

DEVICE DESCRIPTION:

Cannulated screws are machined, metallic screws with a cannulation that are self drilling and self tapping, which can be guided into position by a guide wire.

Cortical and cancellous screws are machined, metallic screws and are self tapping.

All screws utilize a hex shaped recess that accepts a standard hex drive. Each type is offered in a variety of diameters and lengths, as well as short, medium, and fully threaded options.

- Materials: The devices are manufactured from 316L Stainless Steel which meets ASTM F138 standards.
- Function: Bone screws functions are to provide immediate stability and temporary fixation during the natural healing process.

INDICATIONS FOR USE:

Cortical Screws are intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneous, femur and fibula.

Large Cannulated Screws (4.5mm diameter and larger) are intended for fracture fixation of large bones and large bone fragments. Diameters 6.5mm and larger are intended for large bones and large bone fragments such as femoral neck fractures; slipped capital femoral epiphyses; tibial plateau fractures; ankle arthrodeses; pediatric femoral neck fractures; intercondylar femur fractures; and subtalar arthrodeses.

Small Cannulated Screws (4.0mm diameter and smaller) are intended for fixation of fractures and non-unions of small bones and small bone arthrodeses. Examples include scaphoid and other carpal fractures, metacarpal and phalangeal fusions, osteotomies, and bunionectomies.

BASIS FOR SUBSTANTIAL EQUIVALENCE:

OrthoPediatrics believes that this system is substantially equivalent to the legally marketed predicate devices based on similarities in design, materials, and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 5 2008

OrthoPediatrics Corp.
% Mr. Gary D. Barnett
V.P. Regulatory & Medical Affairs
210 North Buffalo Street
Warsaw, Indiana 46580

Re: K082949
Trade/Device Name: OrthoPediatrics Bone Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: September 29, 2008
Received: October 2, 2008

Dear Mr. Barnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K082949

Device Name: OrthoPediatrics Bone Screws

Cortical Screws are intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneous, femur and fibula.

Large Cannulated Screws (4.5mm diameter and larger) are intended for fracture fixation of large bones and large bone fragments. Diameters 6.5mm and larger are intended for large bones and large bone fragments such as femoral neck fractures; slipped capital femoral epiphyses; tibial plateau fractures; ankle arthrodeses; pediatric femoral neck fractures; intercondylar femur fractures; and subtalar arthrodeses.

Small Cannulated Screws (4.0mm diameter and smaller) are intended for fixation of fractures and non-unions of small bones and small bone arthrodeses. Examples include scaphoid and other carpal fractures, metacarpal and phalangeal fusions, osteotomies, and bunionectomies.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K082949